



Testimony
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Subcommittee on National Security, Emerging
Threats, and International Relations
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Update on Anthrax Detection Methods

Statement of

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Good afternoon, Chairman Shays and members of the Subcommittee. I am Dr. Richard Besser, Director of the Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER) at the Centers for Disease Control and Prevention (CDC). On behalf of CDC, I am pleased to provide this testimony to update you on our efforts to improve the government's ability to accurately detect anthrax inside a building.

CDC is part of the Department of Health and Human Services (HHS). CDC's responsibility is to provide national leadership in the public health and medical communities in a concerted effort to detect, diagnose, respond to, and prevent injury and illnesses, including those that occur as a result of a deliberate release of biological agents.

CDC and HHS are preparing the nation to respond to a whole range of threats to public health whether natural disasters or acts of bioterrorism. We are strengthening the state and local public health infrastructure, expanding lab capacity, stockpiling life-saving countermeasures for use in emergencies, and deploying CDC staff to respond to public health emergencies and other events. Based on CDC's experience in the anthrax attacks of 2001, we have developed and made available on our Web site¹ a wealth of information about anthrax for workers, responders, clinicians, citizens and others. It includes information about symptoms, transmission, prevention and treatment among other topics. This

¹ CDC, Emergency Preparedness & Response: Anthrax, <http://www.bt.cdc.gov/agent/anthrax/>

information is updated as new scientific information becomes available, and after a recent incident in which a New York City resident was exposed to anthrax while handling animal hides, CDC added new information about the potential risk from such activities.

In April 2005, CDC provided testimony before this Subcommittee describing CDC's response to the anthrax attacks of 2001 and subsequent efforts to improve techniques for conducting environmental sampling to detect anthrax and laboratory analysis to confirm its presence. My testimony today will provide an update on CDC's activities since that hearing to enhance environmental sampling and lab analysis methods.

CDC's Unique Expertise in Environmental Microbiology

CDC continues to play a unique role in environmental microbiology, developing faster and more accurate assays to detect infectious agents, providing accurate assessments of health risks from these agents in the environment, and providing technical input on re-occupancy issues. Most federal, state, and local public health agencies have limited experience planning and implementing the collection and testing of environmental samples or in studying the physical characteristics of pathogens in the environment. CDC's central role in the detection and containment of public health emergencies of federal importance establishes its key role in the integration of environmental microbiology into outbreak investigations and emergency response.

As discussed during our testimony before this panel in April 2005, method validation for microbial agents is technically challenging, involving extensive and repetitive tests to verify collection efficiencies, recovery efficiencies, effects of storage, temperature and other factors, and for various combinations of methods at various test concentrations. This process is further complicated when working with select agents.

There is enormous demand for services and better and faster ways to detect microbial threats in the environment – due to terrorism, molds in buildings, and emerging infectious disease threats – and, there is a proliferation of sampling devices nationally, both in the community (BioWatch) and in facilities (U.S. Postal Service Biological Detection Systems).

In the process of developing environmental microbiology priorities, CDC arranged for external peer review of the priorities identified by a CDC environmental microbiology working group to ensure that CDC received important objective scientific feedback. The May 10, 2005, external peer review meeting, titled *Enhancing Environmental Microbiology at CDC*, which included a panel of ten reviewers, resulted in unambiguously favorable feedback on the objectives that had been outlined for the program. All individual reviewers expressed support for the concept that environmental microbiology research, as a component of CDC's preparedness activities, is consistent with the CDC

mission to protect public health. Additionally, all reviewers responded that CDC should enhance its capabilities and expand partnerships in environmental microbiology. One of the three key focus areas identified for CDC's expanded environmental microbiology program is the identification of priority agents, which includes developing rapid and effective sampling strategies and sensitive methods of recovery from the environment. The other two focus areas relate to determining the risk of infection and developing techniques and procedures to reduce risk.

Improving Environmental Sampling Strategies

During the response to the 2001 anthrax attacks, CDC relied on targeted (also known as epidemiologically driven) sampling strategies to determine where environmental samples should be collected within buildings. Incident-specific details such as epidemiologic data, interviews with U.S. Postal Service personnel, and understanding of the mail handling process, were used to help identify locations considered most likely to be contaminated so that environmental samples could be collected at targeted locations within a facility. CDC continues to believe that a targeted sampling strategy is the most rapid, efficient, and successful approach when information is available on the path and/or the vehicle of introduction of the suspect infectious agent.

However, as noted in testimony at the April 2005 hearing, CDC agrees that there is a need to further develop probabilistic sampling approaches (i.e. using random

sampling and statistical inferences) to provide additional sampling strategy tools. In 2005, CDC developed and funded a project titled *Developing a Probabilistic Sampling Tool Kit for Initial Response Sampling*, which began in early 2006, to directly address this need. Under this project, CDC is partnering with the Department of Energy's Pacific Northwest National Laboratory (PNNL) to use the lab's "Visual Sample Plan" (VSP) software tool as a platform for this approach. The VSP software facilitates importing facility floor plans, and it assists investigators with overlaying a grid on facility surfaces for selection and tracking of random sampling locations. This project will result in the creation of a sampling tool kit that will be available to field investigators to guide them through the steps needed to perform probabilistic sampling and to manage the documentation for the sampling. As noted by the Government Accountability Office (GAO), this supplemental approach is appropriate in certain circumstances where targeted sampling results were negative and where statistical inferences and random sampling approaches are needed to increase confidence that contamination is not likely to be present.

CDC is coordinating with the Environmental Protection Agency (EPA) as the project develops to ensure that the sampling strategy platform and software developed for initial assessment can then be handed off for subsequent use by EPA and others involved with facility remediation and restoration efforts. The goal is to design the probabilistic sampling tool kit it to support further

customization by EPA to incorporate probabilistic sampling features that can be used with characterization and clearance sampling.

Improving and Validating Sampling Protocols

CDC agrees that validation of sampling protocols is an important objective, and we continue to support efforts to validate components of the detection process. As stated at the April 2005 hearing, CDC continues to believe that full validation of every possible scenario would be impractical and could not take the place of scientific judgment and evaluation of the specific event. Recent, CDC developments related to improving testing protocols are as follows:

Laboratory Studies

CDC researchers evaluated a protocol to recover *Bacillus anthracis* spores using macrofoam swabs. The resulting study, currently pending publication, evaluated the accuracy, precision, reproducibility, and limit of detection associated with the removal of spores from a steel surface using the macrofoam swabs.

CDC researchers evaluated the recovery of *Bacillus anthracis* spores from a smooth non-porous surface using rayon/polyester gauze wipes. The study, which is expected to be presented later this month, evaluated the accuracy, precision, reproducibility, and limits of detection of this recovery method. The study is part of an ongoing effort to evaluate various wipe sampling materials.

CDC researchers examined the effects of different sample filter material and extraction methods on environmental air sampling results for *Bacillus subtilis* spores used as a *Bacillus anthracis* simulant. This research found that MCE (3 micron pore size mixed cellulose ester) and PTFE (1 micron pore size polytetrafluoroethylene) filters in combination with lab procedures to vortex (spin) and shake the samples to extract the spores demonstrated the best performance. A peer reviewed journal article was published on this topic in 2005.²

Laboratory Response Network Enhancements

The Laboratory Response Network (LRN) is a national network of hospitals, state and local public health, federal, military, veterinary, agriculture, food and environmental testing laboratories that provide diagnostic capacity to respond to biological and chemical terrorism and other public health emergencies. The LRN recently developed a multiplex technology (via the BioPlex instrument) which uses PCR (polymerase chain reaction) for nucleic acid detection and amplification to detect DNA from 8 agents (including *Bacillus anthracis*) in a single test—hence the name multiplex. The assay has been optimized for use with environmental samples and will soon be used by the Department of Homeland Security's (DHS) BioWatch Program. The BioPlex procedure goes beyond the currently used standard PCR approach that usually detects only a

² Burton, N.C, Grinshpun, A.A., and R. Hornung. 2005. The effect of filter material on bioaerosol collection of *Bacillus subtilis* spores used as a *Bacillus anthracis* stimulant, J.Environ. Monit. 2005 May; 7(5):475-80.

single product that is specific for one target agent. Using the multiplex approach, multiple threat agents can be tested for simultaneously in a single reaction vial, saving time and freeing up laboratory testing capacity. This is particularly important when dealing with credible threats involving “unknown” infectious agents. These lab-based detection assays will be linked to the improved sampling methods, which are being developed by CDC in collaboration with interagency partners. The updated protocols will be made available on the LRN’s secure Web site, which serves more than 1900 end-user scientists and counter-terrorism coordinators.

The LRN also has made advances in electronic data exchange to facilitate the rapid communication of laboratory test results in an emergency situation through the development and deployment of the LRN Results Messenger. This information technology application uses vocabulary standards and specific security measures to support secure bi-directional transmission of data from an LRN member to the CDC. Further guidance has been provided to LRN members through related notification and data messaging policies, which define the types of data that are required to be submitted to CDC and the timeline for submission.

Collaborative Studies

CDC continues to support research to evaluate environmental sampling methods for *Bacillus anthracis* in collaboration with other Federal agencies.

Dugway Study

CDC is funding research that is underway at the U.S. Army's Dugway Proving Ground in Utah to improve environmental exposure sampling methods. This study uses three surface concentrations and three air concentrations of *Bacillus anthracis* (*Sterns strain*) and will allow for estimates of the lower limits of detection for the sampling methods. The work is conducted in a chamber specifically designed for aerosol studies and is designed to:

- a) Determine the efficiency of three surface sampling methods (wet swab, wet wipe, and surface vacuum filter sampling) on two types of surfaces (stainless steel and carpet);
- b) Determine the efficiency of three air sampling methods (Andersen single stage impactor, PTFE (Teflon) filters, and gel filters);
- c) Determine the overall precision of the methods, encompassing sample collection, sample extraction, and sample analysis;
- d) Determine intra-lab variability and sample transport factors; and
- e) Determine the additional sampling collection efficiency of passing over a surface multiple times.

The research is well underway, and a journal article has been drafted which presents information on how the chamber operates and the uniformity of spore deposition in the chamber.

Sandia Study

CDC and EPA are collaborating with the Sandia National Laboratories in New Mexico on a DHS-funded effort to evaluate current surface sample and extraction methods. The study evaluates current surface sample and extraction methods. The purpose of the testing was to:

- a) Determine the efficiency of three surface sampling methods (wet swab, wet wipe, and surface vacuum filter sampling) on four types of surfaces (2 non-porous - stainless steel and painted wallboard; and 2 porous – carpet and bare concrete);
- b) Determine the overall collection efficiency of the methods, encompassing sample collection, sample extraction, and sample analysis; and
- c) Determine if collection efficiencies are a function of the concentration of spores on the surface being tested.

All of this work was completed in 2005, and the first publication on swab sampling efficiencies is currently in peer review. Two separate publications are being prepared on the evaluations of wipes and vacuum methods.

Coordination and Collaboration

Inter-agency communication is important given the shared responsibilities that CDC maintains with EPA, FBI, DOD, and others. CDC participated in and co-sponsored a number of meetings over the year to coordinate on sampling issues.

These include: a June 13-14 Airport Preparedness Workshop in Livermore, California; and a July 19-20, 2005 meeting on "Sampling Strategies for Building Decontamination" hosted by EPA at Research Triangle Park, North Carolina; and a more recent EPA "Decontamination Workshop" in Washington, D.C. on April 26-27, 2006. CDC and EPA coordinated closely on environmental sampling during the recent New York City anthrax case involving the handling of contaminated animal hides. CDC is currently planning to host a summer 2006 meeting in Atlanta to further discuss sampling issues. CDC is also involved in planning for the October 2006 Second Annual National Conference on Environmental Sampling and Detection for Bio threat agents in New York City. Staff from CDC and EPA's National Homeland Security Research Center (NHSRC) recently met to review their respective environmental microbiology programs, share information, identify common interests and goals, and enhance collaboration inter-agency efforts. This meeting included discussions of sampling and validation issues.

In addition, the LRN helped establish and actively participates in the DHS-sponsored Integrated Consortium of Laboratory Networks (ICLN), which was officially convened in April 2005 by interagency Memoranda of Understanding involving collaboration with ten other federal partners. Current partners include the Departments of Agriculture, Commerce, Defense, Health and Human Services, Homeland Security, Interior, Justice, State, and EPA. The ICLN is an important new program for integrating activities between existing and developing

domestic laboratory networks, including the LRN, in order to identify and address gaps that are not currently being addressed by any of the member networks individually and to better define the roles of the networks for each phase of response in order to improve coordination among federal agencies.

Related Efforts

- CDC developed and funded a project in 2005 titled *Assessment of State of the Art Environmental Sampling Methods for Priority Biological and Chemical Terrorist Agents*. The purpose of this project is to: (1) develop a template and database for identifying, organizing, and evaluating information on existing environmental sampling methods for a given agent; and (2) to use the template to collect available information for *Bacillus anthracis* and for the chemical agent sarin. The template categorizes available methods into four validation status categories. Once the project is completed, the results will be shared and evaluated and the approach finalized so that it can be used for systematically gathering information on other priority agents.
- CDC is partnering with Defense R&D Canada Suffield and the Technical Support Working Group (TSWG), and the Federal Protective Service (FPS) to improve understanding of how contamination is spread in the scenario involving the opening of a letter containing anthrax spores. The results will be used to objectively assess guidelines for minimizing the

exposure risk to both a person opening a letter and to other persons in the vicinity.

- CDC is partnering with the U.S. Army Edgewood Chemical and Biological Center, the FBI, and EPA and to evaluate the risks of re-suspension of *Bacillus anthracis* spores from the outsides of retrieved letters known to be cross-contaminated from the events of 2001. The results will be used to improve understanding of the risks of cross-contamination.

Conclusion

Robust environmental microbiology capabilities are essential for detecting and analyzing anthrax and other pathogens in the environment so that they can be quickly characterized, which permits public health officials to react appropriately, law enforcement officials to initiate timely investigations and for environmental officials to properly remediate contaminated surfaces. CDC has learned a lot since the anthrax attacks of 2001 about sampling and analyzing for anthrax, and we continue to learn more so that our response to future incidents will be as fast and effective as possible.

This concludes my testimony. I would be happy to answer any questions you may have.